K103902

PERUSAHAAN PELINDUNG GETAH (M) SDN BHD
(Company No. 169997-P)
Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat,
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APR 2 2 2011

Reg. No. 322408 MP23

We are an ISO 13485 Certified Glove Manufacturing Facility – Protection is in Our Name

510(K) SUMMARY

Applicant: PERUSAHAAN PELINDUNG GETAH (M) SDN BHD

Address Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat
Senawang Industrial Estate, 70450 Seremban,
Negeri Sembilan, Malaysia.

Phone No. 60-6-6772781 Fax No. 60-6-6772780

Contact Person Lim Kwee Shyan

Date of Summary 2nd December, 2010

Device Information

Trade Name	RUBBERCARE POWDER FREE LATEX EXAMINATION GLOVE, BLUE COLOR
Common Name	POWDER FREE LATEX EXAMINATION GLOVE, BLUE COLOR
Classification Name	Patient Examination Gloves

Claim of Equivalence

The device is a class I latex patient examination gloves 21 CFR 880.6250,Patient Examination Glove, 80LYY which is made powder-free by a process of on-line polymer-coating, meets all the requirements of ASTM standard D 3578-05 and *is substantially equivalent in safety and effectiveness to the predicate device K011271 Powder Free Latex Examination Glove, Blue Color.*

Device Description

It is the powder-free variation of the class I latex patient examination gloves made by on-line polymer-coating. The process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder. It is particularly suitable to users who prefer a powder-free work environment or who may be sensitive or allergic to the powdered version of the same gloves.

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Intended Use of Device

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Technological Characteristics

Following is a table showing the measured parameters of the gloves (e.g. lengths, thickness, widths, physical properties, protein contents, etc) as compared to ASTM. Also data that meets FDA biocompatibility, pinhole, powder-free and any other requirements.

Parameter	ASTM Specifications	Standard References	Measured Values	*Predicate Device K011271*
Length, mm	230 min.	ASTM D3578-05	290mm-305mm	290mm min
Thickness (palm), mm	0.08 min.	ASTM D3578-05	0.20mm-0.24mm	0.20mm-0.24mm
Thickness (finger), mm	0.08 min.	ASTM D3578-05	0.23mm-0.26mm	0.23mm-0.25mm
Width (size: Small), mm	80 ± 10	ASTM D3578-05	82 mm – 85 mm	82 mm – 85 mm
Width (size: Medium), mm	95 ± 10	ASTM D3578-05	89 mm – 94 mm	89 mm – 94 mm
Width (size: Large), mm	111 ± 10	ASTM D3578-05	103 mm – 105 mm	103 mm – 105 mm
Tensile Strength, Before Aging, Mpa	18 min.	ASTM D3578-05	23.1 Mpa	18 Mpa min
Tensile Strength, After Aging, Mpa	14 min.	ASTM D3578-05	29.6 Mpa	14 Mpa min
Ultimate Elongation, Before Aging, %	650 min.	ASTM D3578-05	770 %	770 %
Ultimate Elongation, After Aging, %	500 min.	ASTM D3578-05	830 %	850 %
Water Extractable Protein, µg/gram	200 µg/glove max.	ASTM D5712-99^{c1}	50 µg/glove and below	50 µg/glove and below
Water Leak Test, Before Aging, AQL	2.5	ASTM D3578-05	1.5 and below	1.5 and below
Water Leak Test, After Aging, AQL	2.5	ASTM D3578-05.	2.5 and below	2.5 and below
Residual Powder (size M), mg/glove	2 mg/glove max.	ASTM D3578-05	2 mg/glove and below	2 mg/glove and below
Biocompatability Test	**ASTM F 720-81**			
Skin Irritation Test	n.a	n.a	Passed*	Passed*
Dermal Sensitization Test	n.a	n.a	Passed*	Passed*

Substantial Equivalence Conclusions.

Based on the nonclinical test data , we certify that our gloves: is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, K011271 Powder Free Latex Examination Glove, Blue Color a Class I glove(21 CFR 880.6250), product code LYY.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 16 2011

Lim Kwee Shyan
Chief Executive Officer Managing Director
Rubbercare Protection Products Sdn Bhd
Lot 110 Lorong Senawang 4/3, Off Jalan Senawang Empat
Senawang Industrial Estate
70450 Seremban,
Negeri Sembilan Darul Khusus
MALAYSIA

Re: K102902
Trade/Device Name: Powder Free Latex Examination Glove, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 5, 2011
Received: April 7, 2011

Dear Lim Kwee Shyan:

This letter corrects our substantially equivalent letter of April 22, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102902

Device Name: Powder Free Latex Examination Glove, Blue Color

Indications for Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Elizabeth F. Claverie-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102902